REMARKS

The amendments set out above and the following remarks are believed responsive to the points raised by the Office Action dated July 14, 2003. In view of the amendments set out above and the following remarks, reconsideration is respectfully requested.

The Pending Claims

Claims 14 and 23 have been canceled, and claims 1-13, 15-22, and 24-34 remain pending.

Claims 1, 2, 4, 6, 9, 12, 25, 27, and 31-34 have been amended to describe the invention more clearly. No new matter has been added, the basis for the amended claim language may be found within the original specification, claims and drawings.

Claims 1, 25, and 31 are supported at, for example, page 13, lines 21-23. Entry of the above is respectfully requested.

The Office Action

For convenience, the following remarks will address the various comments and rejections in the same order they were raised in the Office Action.

Election/Restriction

The Official Action mailed July 14, 2003 asserts there are two distinct inventions (identified as Groups I - II) claimed in the referenced application. The Official Action asserts that the groups are independent and distinct and would require independent searches and that the searches for the inventions would not be coextensive.

The Official Action also indicates during a teleconference with the undersigned on June 26, 2003 a provisional election was made "without traverse" to prosecute the invention of Group I. While the undersigned agrees Group I was provisionally elected for prosecution, the undersigned does not agree the election was made without traverse.

ELECTION OF GROUP WITH TRAVERSE

In order to comply with the requirements of the Patent and Trademark Office, Applicants provisionally elect, *with traverse*, Group I (claims 1-13, 15-22, and 31-34) drawn to a filter and filter device for processing biological fluid.

DISCUSSION REGARDING RESTRICTION

The restriction is improper. The claims of Group I relate to a filter and filter device including two filter elements, and in accordance with independent claim 1, one filter element has a surface having a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element, and the claims of Group II relate to a method for processing a biological fluid comprising passing a leukocyte-containing plasma-rich fluid through a filter including two filter elements wherein one filter element has a surface having a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element. Thus, any search and consideration of the claimed subject matter of Group I will likely overlap and encompass that for the claimed subject matter of Group II. Accordingly, the searches for these two groups of claims cannot in any way be said to be completely "independent." This does not mean that the claims necessarily stand or fall together, but the overlapping nature of the searches remains and mitigates against a restriction requirement.

Examination of the patent application would be most expeditious by examining all pending claims together. As Section 803 of the MPEP requires,

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct and/or independent inventions.

The restriction requirement is improper because the Examiner has not shown that a search and examination of the entire application would, indeed, cause a *serious* burden, as required by Section 803 of the MPEP for proper restriction. In fact, a serious burden would arise only if examination of the patent application were restricted to one of the claim groups. Filing additional patent applications containing the non-elected claims would unnecessarily burden (1) the Patent and Trademark Office, since it must assume the additional labor involved in examining at least two separate applications; (2) the public, since it will have to analyze at least two patents (assuming the subject matter of each claim group is found patentable) to ascertain all of the claimed subject matter; and (3) the Applicants, since the Applicants must bear the substantial financial burden and delays associated with prosecution of multiple patent applications and the payment of maintenance fees for multiple patents.

While the inventions defined by the claims may be distinct and independent, there is no demonstration that the search and examination of all the pending claims would entail a serious burden to the Examiner. In particular, it is submitted that any additional burden on the Examiner in considering Groups I and II together is not so serious as to require

restriction, and therefore, Applicants respectfully request withdrawal of the restriction requirement.

Applicants further submit that the present amendment to the independent claims in Groups I and II further reinforces any search and consideration of the claimed subject matter of Group I will likely overlap and encompass that for the claimed subject matter of Group II.

Claim Rejections

Claims 1, 2, 7-10, 12, 16, and 31 were rejected under 35 U.S.C. §102 as anticipated by European Patent Application No. 0,606,646 A1 (hereinafter referred to as "EP '646").

Claims 1-13, 15-22, and 31-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent Application No. 0,267,286 A1 (hereinafter referred to as "EP '286") in view of European Patent Application No. 0,630,675 A1 (hereinafter referred to as "EP '675").

Each of these rejections is separately and respectfully traversed.

The references, whether taken individually, or the combination of EP '286 and EP '675, fail to teach or suggest either a filter comprising at least two filter elements, wherein the surface of one filter element is substantially non-hydroxylated and has a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element (claim 1), or processing a biological fluid by passing a leukocyte-containing plasma-rich fluid through such and obtaining a filtered plasma-rich biological fluid substantially free of leukocytes and platelets (claim 25).

Additionally, the references, whether taken individually, or the combination of EP '286 and EP '675, fail to teach or suggest a filter comprising at least two filter elements, wherein the surface of one filter element is substantially non-hydroxylated and has a greater number of carboxyl groups relative to the bulk of the element and the surface of the other filter element is hydroxylated relative to the bulk of the element (claim 32).

Independent claims 1 and 25 have been amended to indicate that the element having a nitrogen-to-oxygen ratio in the range from at least 0.01 to less than about 1.00 has a surface that is substantially non-hydroxylated, and independent claim 32 has been amended to indicate the element having a greater number of carboxyl groups relative to the bulk of the element has a surface that is substantially non-hydroxylated, thus obviating the rejection in view of EP '646, and the rejection over EP '286 in view of EP '675.

EP '646 merely discloses that in the filter material of the invention, the surface of the porous element has both basic functional groups and nonionic hydrophilic groups, wherein the

molar ratio of the basic functional groups to the nonionic hydrophilic groups is in the range of 0.6 to 6 (page 5, lines 49-51). There is no disclosure or suggestion anywhere in the specification (that includes Examples 1-17 and Comparative Examples 1-12), of either a filter including at least two elements wherein the surface of one filter element is substantially non-hydroxylated and has a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element, or processing a biological fluid by passing a leukocyte-containing plasma-rich fluid through such a filter and obtaining a filtered plasma-rich biological fluid substantially free of leukocytes and platelets.

EP '286 merely discloses a filter element according to the invention comprises a plurality of fibers, each comprising a body portion and a peripheral surface portion, each containing nonionic hydrophilic groups and nitrogen-containing basic functional groups at least in the peripheral surface portion, the peripheral surface portion having a basic nitrogen atom content of from 0.2 to 4.0% by weight (page 8, lines 5-13). There is no disclosure or suggestion anywhere in the specification (that includes Examples 1-11 and Comparative Examples 1-7), of a filter including at least two elements wherein the surface of one filter element is substantially non-hydroxylated and has a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element, or processing a biological fluid by passing a leukocyte-containing plasma-rich fluid through such a filter and obtaining a filtered plasma-rich biological fluid substantially free of leukocytes and platelets. There is also no disclosure or suggestion anywhere in the specification of EP '286 of a filter comprising at least two filter elements, wherein the surface of one filter element is substantially non-hydroxylated and has a greater number of carboxyl groups relative to the bulk of the element and the surface of the other filter element is hydroxylated relative to the bulk of the element.

EP '675 discloses three-dimensionally reticular porous members according to the invention are treated by cationic treatment and surfactant treatment (e.g., page 5, lines 9-10; page 6, line 16). Cationic treatment is defined at page 5, lines 9-18, and exemplary surfactants are described at page 6, lines 23-25. Again, there is no disclosure or suggestion anywhere in the specification (that includes Examples 1-10 and Comparative Examples 1-7), of a filter including at least two elements wherein the surface of one filter element is substantially non-hydroxylated and has a nitrogen-to-oxygen ratio in the range of from at least 0.01 to less than about 1.00, and the surface of the other filter element is hydroxylated relative to the bulk of the element, processing a biological fluid by passing a leukocyte-containing plasma-rich fluid through such and obtaining a filtered plasma-rich biological fluid substantially free of leukocytes and

platelets. There is also no disclosure or suggestion anywhere in the specification of EP '675 of a filter comprising at least two filter elements, wherein the surface of one filter element is substantially non-hydroxylated and has a greater number of carboxyl groups relative to the bulk of the element and the surface of the other filter element is hydroxylated relative to the bulk of the element.

Additionally, applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness in regard to the present invention. The present invention relates to a filter that *inter alia*, minimizes the passage of platelets therethrough. EP '286 emphasizes the invention relates to a filter that "hold[s] down the loss of platelets to a minimum" (page 6, lines 9-10), i.e., the filter allows platelets to pass therethrough. Thus, one would not be led from EP '286 to produce a filter that minimizes the passage of platelets therethrough. EP '675 discloses a filter for separating leukocytes, and separating leukocytes and platelets. One of ordinary skill in the art would not be led from the platelet passing filter of EP '286 to the filter of EP '675, and, as noted above, even if one could be led from the teachings of EP '286 to EP '675, there is no teaching or suggestion in these disclosures leading one to the presently claimed invention.

Accordingly, the disclosure of EP '646, and the disclosure of EP '286 in view of the disclosure of EP '675, fail to teach or suggest the claimed invention, and thus, the rejections cannot be maintained.

The dependent claims are also allowable, as they depend from the novel and non-obvious independent claims. Additionally, there is no teaching or suggestion in the cited references of a filter with additional elements as claimed in claims 2-6, 33, and 34, or a method of processing a biological fluid using a filter with additional elements as claimed in claim 27. Moreover, while the Official Action states the element disclosed in EP '646 "will have" the claimed zeta potential and critical wetting surface tension, and the elements disclosed in EP '286 and EP '675 would have similar properties (zeta potential, critical wetting surface tension, and C3a removal) to the claimed invention, the Official Action does not explain why this is so. Illustratively, EP '675 teaches a "cationic treatment" and refers to "maintaining a positive charge of the filter for a long period of time" (page 5, lines 9-18), which would appear to provide a positive zeta potential at physiological pH.

For the reasons set forth above, reconsideration of the rejections is respectfully requested.

Conclusion

In view of the amendment and remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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JMJ/jj

Amendment or ROA - Regular (Revised 7/29/03)